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EXAMINER

TSAY, MARSHA M

ART UNIT	PAPER NUMBER
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1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,277	Applicant(s) MILANOVA ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,11-16,20-24,26-28,32-34,36-43,49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,11-16,20-24,26-28,32-34,36-43,49 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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This Office action is in response to Applicants' remarks received August 17, 2009.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 1-2, 5-10, 17-19, 25, 29-31, 35, 44-48, 50 are canceled. Claims 3-4, 11-16, 20-24, 26-28, 32-34, 36-43, 49, 51-53 are currently under examination.

Priority: The request for priority to provisional application 60/401782, filed August 8, 2002, and provisional application 60/390126, filed June 21, 2002, is acknowledged.

The indicated allowability of claims 3-4, 11-16, 20-24, 26-28, 32-34, 36-43, 49, 51-53 is withdrawn upon further consideration of the previously cited art. The rejection of the claims under 35 U.S.C. 103(a) is below.

Objections and Rejections

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36, step (i), recites the protein micellar mass has a protein content of at least 90 wt% (N x 6.25) on a dry weight basis, wherein said recovered protein micellar mass has a protein

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content of at least 100 wt% (N x 6.25). It is unclear which wt% the protein content is. For purposes of examination, however, claim 36, step (i), has been interpreted as a protein content of at least 90 wt%.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 11-16, 24, 26-28, 32-34, 36-43, 49, 51-53 are rejected under 35 U.S.C. 103(a) as being obvious over Murray (US 6005076; IDS, previously cited) in view of Rossi et al. (Lebensmittel-Wissenschaft Und-Technologie 1982 Istituto Di Technologie Alimentari, Univ. Degli Studi Di Milano, Via Celoria 2, 20133, Milan Italy 15(5): 309-312; IDS 07.25.06; previously cited).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the

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application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(1)(1) and § 706.02(1)(2).

In Example 3 (col. 7, lines 60-67), Murray discloses a process of initially preparing a protein isolate using a meal prepared from the cold pressing of canola seeds to give a consistency similar to canola meal, followed by a protein extraction and recovery process (as described in Example 2). According to Murray, the "canola meal" may be any canola meal resulting from the removal of canola oil from canola seed (col. 2-3, lines 66-2). In Example 2, Murray discloses that meal from rapeseed containing 32.5% protein, 10.1% fat and 6.1% moisture was extracted with an aqueous salt solution and agitation (col. 7 lines 37-40). It would be reasonable for one of ordinary skill to recognize that the initial rapeseed meal having a moisture content of 6.1% would be essentially a dried meal product that is desolventized. The aqueous meal/salt solution was mixed for 2 hours at 25°C to remove residual meal and then chilled to 8°C followed by centrifugation (col. 7 lines 5, 40-43). Murray discloses the aqueous salt solution with an ionic strength value of less than 0.8 and within the range of 0.3 to 0.6 (col. 8, lines 62-63), a pH range of 5.3 to 6.2 (col. 8, line 66-67), and wherein the aqueous protein solution has a concentration of about 10-100 g/L of protein (col. 9, lines 1-3). In addition, Murray discloses that the formation of protein isolates into micelles is achieved optimally at pH values of 5.3 to 6.2 (col. 3, lines 46-50). After separating the aqueous protein solution from the residual oil seed meal, Murray discloses a process step for increasing the protein concentration using a selective membrane

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technique, diluting the concentrated protein solution by 15 fold at 6 ° C to form protein micelles, settling the protein micelles, and recovering the protein mass to provide a dried proteinaceous powder having a protein content of at least 90 wt % (col. 7, lines 12-30, col. 8, lines 31-61).

Murray does not explicitly teach a desolventized oil seed meal under vacuum (i.e., the steps of 3(b) and 3(c)) or a continuous mode of operation.

Rossi et al. disclose that to obtain a protein meal, an initial oil-extraction process is used to obtain a "cake" that is rich in protein. Rossi et al. further disclose a desolventizing under vacuum technology can be performed at 40°C of said cake to obtain a protein meal (p. 309, 310 Figure 1, p. 311 column 2).

The instant claims are essentially drawn to a process of preparing a protein isolate comprising processing a desolventized oil seed meal. The desolventized oil seed meal is obtained by the process described in claims 3(a)-3(c). The actual process to recover protein isolate from the desolventized oil seed meal is described in claims 3(d)-3(i).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray of obtaining a protein isolate by first crushing canola seeds (claim 3a), substituting the oil-extraction process (claim 3b) and desolventizing under vacuum process (claim 3c) of Rossi et al. to obtain a desolventized oil seed meal and then processing said desolventized oil seed meal to obtain a protein isolate by extracting said desolventized oil seed meal to cause solubilization and to form an aqueous protein solution having a pH of about 5-6.8, maintain the aqueous solution at an ionic strength and pH range that is suitable for the formation of protein micelles (claims 3-4, 11-16, 24, 32-34, 36-37), increase the protein concentration (claim 3), dilute the concentrated protein solution to induce the

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formation of protein micelles (claim 3-4, 11-16, 24, 32-34, 36-37), settle the protein micelles, and recover the protein micelles to make a dry proteinaceous powder having a protein content of at least 90 wt % (claim 3-4) because Murray provides and suggests motivation for a method of preparing a protein isolate from a desolventized oil seed meal and Rossi et al. teach a desolventized oil seed meal under vacuum.

Murray does not specifically disclose that steps (d) to (i) of claims 3-4 are effected in a semi-continuous or continuous mode of operation.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, for the steps of (d) through (i) of the process of making a canola protein isolates as taught by Murray, to have been effected in a continuous mode of operation in order to increase the efficiency and overall production capacity of the system. One of ordinary skill in the art would have been motivated to make the process of Murray run in a continuous or semi-continuous mode in order to achieve the maximum efficiency of the production system, thereby increasing production of said protein isolate and increasing financial returns.

Further, the court has held that a claimed continuous operation would have been obvious in light of the batch process of the prior art. *In re Dilnot*, 319 F.2d 188, 138 USPQ 248 (CCPA 1963). See also MPEP 2144.04.

Regarding claims 24, 42-43 (i.e. salt is subsequently added to the resulting aqueous protein solution to provide an aqueous protein solution having an ionic strength of at least 0.10), it should be noted since Murray discloses that extracting canola oil seed meal is effected using an aqueous salt solution having an ionic strength of at least 0.2 and a pH of about 5-6 (col. 3 lines 9-11, lines 40-41), it is believed that salt is added to the water at some point during the extraction

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process. Further, it is known that selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See also MPEP 2144.04. In this instance, it would be reasonable for one ordinary skill to know that the addition of salt to an aqueous solution would also require a dialyzing step in order to eliminate the salt from the concentration protein solution (claims 42-43).

Regarding claim 26, 49 (i.e. said concentration step is effected by ultrafiltration), as noted above, Murray discloses a process step for increasing the protein concentration using a selective membrane technique. It would be reasonable for one of ordinary skill to know that an ultrafiltration technique is within the scope of a selective membrane technique. The normal desire of scientists to improve upon what is already generally known provides the motivation to determine which specific membrane should be used to produce a protein isolate which will have the highest protein content, i.e. greater than 100 g/L, 200 g/L, etc.

Regarding claims 27-28 (i.e., said concentrated protein solution is warmed to a temperature of at least 20°C), Murray discloses the concentration of the protein solution may be effected at any convenient temperature, i.e. 20°C to 45°C (col. 4 lines 66-67 to col. 5 lines 1-5). Therefore, it would be reasonable for one of ordinary skill to be motivated to determine which conditions will yield the highest protein concentration in order to obtain a protein isolate with the highest protein content.

Regarding claims 38-41, 51-53 (i.e., recovering additional quantities of protein isolate from the supernatant by concentrating the supernatant to a protein concentration of about 100 to

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400 g/L), as noted above, Murray discloses increasing the protein concentration; therefore, it would be reasonable for one of ordinary skill to determine at which protein concentration the supernatant should be at (i.e. greater than 100 g/L, 200 g/L, etc.) in order to recover a protein micellar mass that will yield a protein isolate with the highest protein content. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP 2144.05. Further, it is known that selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). See also MPEP 2144.04.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6005076; IDS, previously cited) in view of Rossi et al. (Lebensmittel-Wissenschaft Und-Technologie 1982 Istituto Di Technologie Alimentari, Univ. Degli Studi Di Milano, Via Celoria 2, 20133, Milan Italy 15(5): 309-312; IDS 07.25.06; previously cited) in view of Cook et al. (US 5254673). The teachings of Murray in view of Rossi et al. are outlined above. Murray discloses that the presence of fat in protein production can lead to discoloration resulting from the co-processing of pigments in the meal with the fat.

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Cook et al. disclose a process for zein protein purification from corn meal. Cook et al. disclose that activated carbon powder can be used to further purify said protein from meal (col. 9 example 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Murray in view of Rossi et al. by adding in the step of incorporating activated carbon powder as suggested by Cook et al. in order to obtain a protein isolate from the canola seed meal (claims 20-23). The motivation to do so is given by Cook et al. which disclose that activated carbon powder can be incorporated into a protein processing method in order to better purify the protein isolate that is obtained from a seed meal.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

December 18, 2009

Marsha Tsay
Art Unit 1656